

K961736

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Pre-Market Notification  
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**VI. 510(k) Summary of Safety and Effectiveness**

**A. Name and Address**

This Summary of Safety and Effectiveness is being submitted by Nobelpharma USA, Inc., 777 Oakmont Lane, Suite 100, Westmont, IL 60559. Their telephone number is (708) 654-9100. The contact person will be the Director, Regulatory Affairs. This summary was prepared on May 1, 1996.

**B. Name of the Device**

This device is generally known as an abutment to an endosseous implant with the trade name BRANEMARK SYSTEM® 17° Angulated Abutment. This submission is a modification to an previously cleared device subject to K944962.

**C. The Predicate Product**

The predicate product used in this Premarket Notification is the previous version of the same device, 17° Angulated Abutment, K944962.

**D. Description of the Device**

The Nobelpharma 17° Angulated Abutment is an abutment used with an endosseous implant. The abutment sits upon the implanted fixture and is used to support prosthetic devices and restore chewing functions in edentulous patients. The only modification is the narrowing of the base and external diameter of the abutment; and narrowing of the diameters of the abutment screws, adding one series of abutments to fit the smaller diameter fixtures previously cleared.

**E. Intended Use of the Device**

The Nobelpharma 17° Angulated Abutment is intended to be used in edentulous patients as an anchor to support a prosthesis.

**F. Comparison of Technological Characteristics**

The technological characteristics between the modified version of the 17° Angulated Abutment and the earlier version are identical. The changes are minor dimensional changes to the diameter of the abutment and abutment screw.